# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

**No. 19-969V**

UNPUBLISHED

| | |
|---|---|
| COLLEEN BLOCK,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: October 29, 2021<br><br>Special Processing Unit (SPU); Off-Table Dismissal; Influenza (Flu); Guillain-Barré syndrome (GBS); *Althen* Prong Three; One-Day Onset; Adaptive Immune Response. |

*Lia Obata Dowd, Dowd & Dowd, P.C., St. Louis, MO, for Petitioner.*

*Jeremy Fugate, U.S. Department of Justice, Washington, DC, for Respondent.*

## ENTITLEMENT DECISION[1]

On July 3, 2019, Colleen Block filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleged that she suffered Guillain-Barré syndrome ("GBS") as a result of an influenza ("flu") vaccine administered on November 10, 2017. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

On April 26, 2021, after consideration of the medical record and other filed evidence, I concluded that Petitioner had experienced the onset of her alleged GBS

[1] Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

symptoms within approximately 24 hours of vaccination – outside of the 3 to 42-day period prescribed for a Table flu/GBS injury – thus, constituting grounds for dismissal of that claim. *See generally* Findings of Fact and Conclusions of Law (ECF No. 25) ("Table Claim Dismissal"). In so doing, I also observed that Petitioner's submission of an expert report from a neurologist, Dr. David Simpson, barely supported even a causation-in-fact version of the claim. But I noted that I would permit both sides to submit additional evidence on the medical acceptability of onset for a non-Table version of the claim. Table Claim Dismissal at 11-13.[3]

Both parties have offered legal responses[4] and expert materials[5] on this issue. Having reviewed these materials in light of my prior opinion, I hereby conclude that Petitioner has not established by a preponderance of the evidence that the onset of GBS within 24 hours of receipt of the flu vaccine is medically acceptable. Therefore, she cannot establish causation-in-fact and her non-Table claim is hereby dismissed.[6]

## I. Evidentiary and Expert Submissions

### A. Respondent's Experts

On June 10, 2021, Respondent filed reports from two experts. The first, Norman Werdiger, M.D., has been employed at the Yale University School of Medicine since 1982 and specifically as a clinical associate professor of neurology since 2006. *See* Werdiger

[3] My prior summary of the relevant procedural history, underlying facts, Petitioner's expert's first report, parties' arguments, applicable legal standards, and my initial analysis concerning the feasibility of Petitioner's off-Table flu/GBS claim are set forth at length in the Table Claim Dismissal, and fully incorporated and relied upon herein.

[4] Petitioner's Brief filed September 1, 2020 (ECF No. 20); Respondent's Brief filed October 30, 2020 (ECF No. 24). While the briefs were filed prior to the Table Claim Dismissal (and are cited therein), those briefs address whether Petitioner has established an off-Table claim.

[5] *See* Expert Report of David Simpson, M.D. dated September 1, 2020, filed as Ex. 13 (ECF No. 21) ("Simpson Rep."); Expert Report of Norman Werdiger, M.D., dated June 4, 2021, filed as Ex. A (ECF No. 27-1) ("Werdiger Rep."); Expert Report of Neil Romberg, M.D., dated June 10, 2021, filed as Ex. N (ECF No. 28-1) ("Romberg Rep."); Supplemental Report of David Simpson, M.D., dated August 29, 2021, filed as Ex. 26 (ECF No. 30) ("Simpson Supp. Rep.").

[6] While this opinion discusses the elements of the record that were emphasized by the parties and that I found most relevant to the outcome, I have reviewed and considered the *entire* record, including all of the literature submitted by both parties. Section 13(a)(1); *see also Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("we generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision"); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("a special master is not required to discuss every piece of evidence in [his] decision") (internal citation omitted), *aff'd*, 601 Fed. Appx. 982 (Fed. Cir. 2015).

Rep. at 2. Dr. Werdiger retired his private neurology practice in August 2019 but continues to provide outpatient general neurological care through his affiliation at Yale. *Id.* In the past five years, he has seen or participated in the treatment of approximately ten patients with GBS. *Id.* He has not authored any publications that inform this case but based his opinion on a review of the relevant literature.

Respondent's second expert, Neil Romberg, M.D., joined Yale University as a fellow in allergy and clinical immunology from 2008 to 2011, then served as an associate professor and the director of Yale's Pediatric Immune Deficiency Clinic from 2011 to 2015. *See* Romberg Rep. at 1. Since 2015, he has served as an assistant professor of pediatrics at the University of Pennsylvania School of Medicine and an attending physician at the Children's Hospital of Philadelphia. *Id.* at 1-2. Dr. Romberg has focused his career on researching the molecular mechanisms, as well as providing appropriate treatment, for immunological disorders. *Id.* He asserted that he is aware of the classic findings as well as the immunological basis of GBS. *Id.* at 1, 5.

Respondent's experts both take issue with an item of literature that was offered in connection with the submission of Petitioner's earlier expert report (and discussed at length in the Table Claim Dismissal), Park. *See* Table Claim Dismissal at 7-8, 11-12. Drs. Werdiger and Romberg both note that although Park describes the South Korean government's compensation of claims for post-vaccination GBS, including instances in which the illness purportedly manifested within two days, approximately one-third of the total cases were not confirmed diagnostically. Additionally, approximately one-tenth of the cases at issue may have been caused by unrelated infections. Werdiger Rep. at 14; Romberg Rep. at 8. Otherwise, these experts argue, the South Korean government's decision to compensate certain cases of purported GBS manifesting less than two days of vaccination does not establish anything with regard to causation. Werdiger Rep. at 14; Romberg Rep. at 8.

Respondent's experts further discussed the pathophysiology of GBS and how that relates to its clinical onset after a triggering event. As they explained, GBS occurs when a genetically susceptible individual encounters an environmental agent which causes an adaptive immune response, including T cells and antibodies, misdirected against specific targets in the peripheral nervous system. The misdirection occurs due to molecular mimicry between amino acid sequences on the proteins of the pathologic/presenting antigens and the similar sequences in the protein components of nerve structures. Romberg Rep. at 6; Werdiger Rep. at 12 (citing K. Sheikh, *Review: Guillain-Barré Syndrome*, 26 Continuum – Peripheral Nerve and Motor Neuron Disorders 1184 (2020), filed as Exhibit D (ECF No. 27-4) ("Sheikh")).

Dr. Romberg opined that the time it would take for this process to result in the onset of GBS could not occur within one day of exposure to the precipitating environmental agent. Rather, the adaptive immune response is "more deliberate," and will involve "a delay between exposure and onset of symptoms," in contrast to the more rapid, but nonspecific, innate immune response. Romberg Rep. at 8, citing C.A. Janeway et al., *Principles of Innate and Adaptive Immunity*, in *Immunobiology: The Immune System in Health and Disease* (5th ed. 2001), filed as Exhibit X (ECF No. 28-11).

Dr. Romberg acknowledged that certain epidemiologic evidence seemed facially to allow for the possibility of a short onset, but he opined that this evidence was ultimately thin and quite limited. One such article, long cited in favor of the flu vaccine-GBS association, reported that a small number of GBS cases observed – 10 out of 532, or 1.8% - manif within two days of vaccination. Romberg Rep. at 7-8, citing L. Schonberger et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976 – 1977*, 100 Am. J. Epidem. 105 (1979), filed as Ex. 19 (ECF No. 21-6) ("Schonberger"). A later meta-analysis of 23 million adverse events reported after flu vaccines, found only 54 instances of GBS - with 51 of them (95%) showing onset within two days. Romberg Rep. at 9, citing D.A. Salmon et al., *Association Between Guillain- Barré Syndrome and Influenza A (H1N1) 2009 Monovalent Inactivated Vaccines in the USA: A Meta-Analysis*, 381 Lancet 1461 (2013), filed as Ex. Y (ECF No. 28-12 ("Salmon"). Importantly, neither Schonberger nor Salmon address whether the timing for this small minority of cases is even medically acceptable. Thus, Dr. Romberg maintained that these findings were inconsistent with what was well understood about GBS's pathologic timeframe, as well as too minimal to be meaningful.

Dr. Werdiger agreed with the above, adding that the timeframe issue could be better grasped by analogizing GBS to another neurological injury also understood to be mediated by an adaptive immune response - acute disseminated encephalomyelitis ("ADEM"). Werdiger Rep. at 12, citing A. Rowhani-Rahbar et al., *Review: Biologically Plausible and Evidence-Based Risk Intervals in Immunization Safety Research*, 31 Vaccine 271 (2012), filed as Exhibit K (ECF No. 27-11) ("Rowhani-Rahbar"). In discussing ADEM, Rowhani-Rahbar writes that "Some neurologic events are immune-mediated in which an immune response involving self-directed antibodies are autoreactive T-cells generated against neuronal epitopes may occur. *Consideration of biologic plausibility of an AEFI [adverse event following immunization] would require a certain period between immunization and onset of symptoms.*" *Id.* at 274 (emphasis added). While there is limited data existing about the shortest possible timeframe between introduction of an antigen, mounting of a subsequent immune response, and the onset of clinical disease, "*an interval of less than 48 h[ours] would seem to be biologically implausible*." *Id.* (emphasis added). As a result, the Centers for Disease Control and Prevention ("CDC"), upon

reviewing an *individual* case of vaccination and ADEM, only considers a potential causal association when onset is *beyond* 48 hours. *Id.* Indeed, more robust epidemiological studies only consider causation potentially present when the onset exceeds five days. *Id.* Dr. Werdiger opined that the same limitations on the timeframe between vaccination and GBS should apply, because of the diseases' similar pathophysiology.

### B. Dr. Simpson's Supplemental Report

In his supplemental report,[7] Dr. Simpson discussed some of the limitations on Park raised by Respondent. He acknowledged that over one-third of the GBS diagnoses discussed by Park were uncertain. Simpson Supp. Rep. at 6. But he maintained that these cases were nevertheless "reviewed thoroughly and concluded as having GBS by experts meeting." *Id.* In so arguing, however, he did not address the other concern that I raised, and Respondent's experts echoed – that pre-vaccination infection could not be excluded as a causative factor in approximately one-tenth of the *total* compensated flu-GBS cases considered in Park. Dr. Simpson also suggested that South Korea's vaccine compensation program "appears to have notable similarities to that employed by the US National Vaccine Compensation Program." *Id*. However, the only discernable similarity is that South Korea's program involves some degree of participation by medical experts.

Dr. Simpson went on to address issues relevant to the timeframe for an aberrant immune response leading to GBS. He acknowledged that the "early onset of neurological symptoms" following vaccination is "atypical," but has nevertheless been reported by other authors such as Schonberger and Salmon. Simpson Supp. Rep. at 5. He further opined that there is precedent for his proposed one-day timeframe, as reflected by the CDC's defined risk interval of 0 – 48 hours between receipt of inactivated flu vaccine and *febrile seizures*. Simpson Supp. Rep. at 6 (citing Rowhani-Rahbar at 273). However, Dr. Simpson did not explain why febrile seizures, rather than ADEM, are a more useful analogue for GBS. And he did not dispute that GBS involves an adaptive immune response, in which it would take time *both* for the adaptive response to mount and *then* for the autoimmune attack to cause symptoms.

[7] Dr. Simpson devoted several pages to addressing other points raised by Respondent's experts, including whether GBS is the correct diagnosis for Petitioner's injury and whether her injury was more likely caused by a preceding diarrheal illness. Simpson Supp. Rep. at 2-5. I have reviewed both parties' positions on those issues, but find them unnecessary to resolve, in light of the dispositive onset issue which is discussed above.

## II. Legal Standard for *Althen* Prong Three

As previously noted, a temporal association alone between vaccination and disease onset "does not suffice to show a causal link" between the two. Table Claim Dismissal at 11 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). Rather, under the third prong set by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005), a petitioner is required to establish a "proximate temporal *relationship*" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281 (emphasis added). That relationship must ultimately be "medically acceptable." *Id.*

To establish this prong, a petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013, *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1329 (Fed. Cir. 2014).

## III. Analysis

Over a year ago, I warned Petitioner that (even despite the fact that within the Vaccine Program, GBS is widely understood to be associated with flu vaccine), a GBS onset *within 24 hours* of receipt of flu vaccine would likely thwart even an off-Table claim. Order to Show Cause (ECF No. 18) (citing *Rowan v. Sec'y of Health & Human Servs.*, No. 17-760V, 2020 WL 2954954 (Fed. Cl. Spec. Mstr. April 28, 2020) (finding that GBS is known to be mediated by autoantibodies produced via the adaptive immune system, and this process, if vaccine-induced, likely takes longer than three days to result in symptoms). Then, in dismissing Petitioner's Table claim, I noted that her expert's first report and supporting literature (chiefly the Park article) "would, if unrebutted, barely support entitlement," but that the short timing was still an area of significant risk that would likely prove to be dispositive. Table Claim Dismissal at 12-13. Respondent has now filed rebuttal evidence on this point, which Petitioner has not overcome.

Petitioner's argument continues to rely solely on one item of evidence - the Park article – to support a one-day onset for GBS after the flu vaccine. But as Respondent's experts have established, Park is not entitled to great weight for the reliability of its

medical findings. Over one-third of the cases (18/48, or 37.5%) considered by Park met only the "lowest level" of diagnostic certainty for GBS, because of incompatible or insufficient testing. Park at 1158. Thus, it cannot be presumed that all cases at issue, whatever the onset, were in fact GBS. Park does not explain why the South Korean government decided to accept the claimed diagnosis in those cases, and Park in fact emphasizes that "complete treatment and testing results need to be obtained" to properly evaluate the incidence of GBS following vaccination. *Id.* at 1158-59. Dr. Simpson has only added that South Korea's program appears to include some degree of medical review, but he has not addressed the standard for compensation[8] or who makes the final determination.[9]

Most importantly, Petitioner has not preponderantly established that from an immunologic standpoint, GBS could acceptably begin in so short a timeframe. On this subject, Dr. Simpson was not persuasive. Notwithstanding his general medical education and expertise treating neurological disorders including GBS,[10] Dr. Simpson lacks the requisite *immunological* background to credibly support the short timeframe. It is reasonable for me to give less weight to his opinion, given his reduced expertise regarding this critical question. *See Rowan*, 2020 WL 2954954 at *18 ( "despite his overall testimonial qualifications, [the petitioner's expert] cannot point to any personal research or direct expertise on the question of the timeframe for vaccine-induced GBS onset").

Dr. Simpson demonstrated his lack of immunological expertise upon attempting to analogize the onset of post-vaccine GBS to that of post-vaccine febrile seizures. Simpson Supp. Rep. at 6 (*citing* Rowhani-Rahbar at 273). The two simply are not comparable, for (as discussed in many prior decisions) the theory of vaccine-induced seizure involves an aberrant *innate* immune response, generating fever and (subsequently) seizure. *See Caredio v. Sec'y of Health & Human Servs.*, No., 2021 WL 4100294, at *30 (Fed. Cl. Spec. Mstr. July 30, 2021) (*citing Ginn v. Sec'y of Health & Human Servs.*, No. 16-1466V, 2021 WL 1558342 (Fed. Cl. Spec. Mstr. Mar. 26, 2021)); *Tembenis v. Sec'y of Health &*

[8] Y. Choe and G. Bae, *Review: Management of Vaccine Safety in Korea*, 2 Clin. Exp. Vaccine Res. 40, 44 (2013), available at https://pubmed.ncbi.nlm.nih.gov/23596589/ (providing that South Korea provides for compensation in cases where vaccine causation is "definite, probable, or *possible*," as defined by the World Health Organization) (emphasis added).

[9] R. Mungwira et al., *Research Article: Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PLOS ONE e0233334, 7 (2020), available at https://doi.org./10/1371/journalpone.02333334 (discussing that some countries have "purely administrative programs" overseen by medical experts, compared to other countries, such as the United States, in which "the final decision on compensation is made by legal experts.").

[10] *See also Q.P. v. Sec'y of Health & Human Servs.*, No. 15-449V, 2019 WL 4013436 (Fed. Cl. Spec. Mstr. July 29, 2019) (finding that Dr. Simpson's limited experience in the Vaccine Program, his work as an expert neurologist merited $500.00 per hour).

*Human Servs.*, No. 03-820V, 2010 WL 5164324, at *15-16 (Fed. Cl. Spec. Mstr. Nov. 29, 2010). This can in fact occur rapidly (since the innate response begins occurring close-in-time to a vaccine's administration) - and thus is inapposite to GBS, which (despite its acute and monophasic course once it becomes clinically evident) "involves the more deliberate adaptive immune system rather than just the rapid actions of innate immune cells." Romberg Rep. at 8.

Respondent's experts, by contrast, more persuasively opined that the understanding of immunologic processes that mediate and drive GBS likely do not occur so quickly after a triggering event. Upon introduction of the foreign pathogen (or vaccine antigen), it takes several days for the activation of the adaptive immune response and the production of antibodies, followed by any autoimmune attack on the peripheral nervous system and resulting clinical manifestations. Romberg Rep. at 6; Werdiger Rep. at 12; *see also Rowan*, 2020 WL 2954954, at *17 (citing *Forrest v. Sec'y of Health & Human Servs.*, No. 14-1016V, 2019 WL 925495, at *6 (Fed. Cl. Spec. Mstr. Jan. 28, 2019) (explaining that these lag and "log" phases are sequential)).

As a final point, I am resolving Petitioner's claim on the papers rather than via hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also v. Hooker Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n. 19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 3 97, 402-03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

Here, Ms. Block has long been made aware that the issue of the timing in her case was likely to be dispositive, directed to my prior rulings on this point, and given several opportunities to provide evidence to support a different result (such as unique circumstances, a more qualified expert, or medical literature supporting an evolving understanding of the immune response that manifests in GBS). She has not done so.

## Conclusion

Petitioner has not established that the onset of GBS within one day of a flu vaccine is medically acceptable under *Althen* prong three. Therefore, she cannot establish causation-in-fact, and her off-Table claim must be dismissed. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[11]

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**
Brian H. Corcoran
Chief Special Master

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.